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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/650,337 | 08/28/2000 | William J. Dower | 16528A-000461US | 8260 |
| 53971 | 7590 | 09/28/2005 | EXAMINER | |
| BIO TECHNOLOGY LAW GROUP 658 MARSOLAN AVE. SOLANA BEACH, CA 92075 | | | WANG, LOUISE Z | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1648 | |

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 09/650,337 | Applicant(s) DOWER ET AL. | |
| | Examiner Louise Wang | Art Unit 1648 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 35,38,45-47,50-55 and 63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 35,38,45-47,50-55 and 63 is/are rejected.
- 7) ☒ Claim(s) 45 and 46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>7 May 2001</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's election without traverse of Group III, drawn to claims 35, 38, 45-47, 50-55, and 63, in the reply filed on July 21, 2005 is acknowledged.

Claims 33, 34, 36, 37, 39-44, 48, 49, 56-62, and 64-73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and inventions, there being no allowable generic or linking claim.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. § 120 is acknowledged. Applicant has complied with conditions for receiving the benefit of an earlier filing date, 20 June 1990.

Information Disclosure Statement

The information disclosure statement (IDS) is filed on 7 May 2001. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Oath/Declaration

The oath or declaration is missing. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

Claim Objections

Claim 46 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 45. Claims 47, 50-52 are objected to under 37 CFR 1.75 as being substantial duplicates of claim 53. Claims 54 and 63 are objected to under 37 CFR 1.75 as being substantial duplicates of claim 55.

When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000.

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Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 35, 38, 45-47, 50-55, and 63 are rejected under 35 U.S.C. 102(e) as being anticipated by Kauffman *et al.* As Applicant indicated, claims 35 and 38 correspond to claims 16 and 34 in US Patent No. 5,723,323; claims 45-47, 50-55, and 63 correspond to claims 1-3, 15, 29, 47, 61, 79, 91, respectively in US Patent No. 5,814,476; and claim 63 corresponds to claim 29 in US Patent No. 5,817,483. The effective filing date for the instant application is June 20th, 1990, which is after November 20th, 1986, the effective filing dates for all of US Patent No. 5,723,323, 5,814,476, and 5,817,483. Thus, these claims are anticipated by Kauffman *et al.*

Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Seed *et al.* (1987).

Claimed invention is a method of isolating a polynucleotide sequence encoding a protein having a predetermined binding property to a ligand.

Seed taught a method of isolation of a cDNA encoding CD2 surface antigens. The ligand for detecting of binding property was T-cell erythrocyte (see title). The construction of a cDNA library of $\approx 3 \times 10^5$ recombinants meets the limitation of synthesizing a diverse population of a randomly generated polynucleotide sequences. The cDNA was inserted into a COS cell expression vector. The ligated DNA was transformed into COS cells for protein expression. The proteins were screened by adherence assays of cells expressing surface antigen to antibody-coated dishes. DNA

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was prepared from adherent cells and transformed into *E. coli*. The resulting colonies were pooled, fused into COS cells, and subjected to a second round of adherence assays. After the third round, DNA was prepared from resulting adherent colonies and transfected into COS cells, which was subjected to indirect immunofluorescent detection. DNA was prepared from confirmed transfected COS cell cultures and digested with restriction enzyme to obtain the coding DNA for CD2 (See Results and Discussion, first paragraph, and Abstract).

Thus, claim 35 is anticipated by Seed *et al.*

Claim 38 is rejected under 35 U.S.C. 102(b) as being anticipated by Oliphant *et al.* (1986).

Claimed invention is a method of producing a diverse population of randomly generated polynucleotide sequences comprising synthesizing a diverse population of randomly generated polynucleotide sequences and inserting them into a population of vectors.

Oliphant *et al.* teaches a method of cloning random DNA. The procedures involve (1) direct cloning of single-stranded oligos into double-stranded DNA molecules; and (2) converting oligos into double-stranded DNA that can be easily inserted into standard vectors or ligation of single-stranded oligos into double-stranded vectors (page 178). Oliphant *et al.* states that this method can be adapted to study the requirements for specific regions of proteins (page 182, last paragraph), which reads on to ligand binding in the instant claim.

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Thus, claim 38 is anticipated by Oliphant *et al.*

Claims 35, 38, 45-47, 50-55, and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Ballivet *et al.* (WO 86/05803).

Claimed invention is method of isolating a peptide with a desired property such as having predetermined binding property to a ligand, isolating its coding polynucleotide sequence, and isolating a polynucleotide with a desired property such as binding to a ligand, comprising production of a diverse population of random polynucleotide sequences and vectors; expressing the vectors in host cells; producing diverse populations of transcription products or peptides; screening for the peptides with ligand binding property; and isolating random polynucleotides encoding such peptides. Such a method is disclosed in the prior art.

Ballivet *et al.* teaches a method for isolating (obtaining) a polynucleotide sequence (DNA, RNA), peptides, polypeptides or proteins by recombinant DNA technique, i.e. modifying host cells containing genes capable of expressing RNAs, peptides, polypeptides or proteins with predetermined properties (page 1, 1st paragraph). Specifically, this reference teaches a method that produces stochastic or random polynucleotide sequences (genes or fragments of genes) by stochastic copolymerization and inserting the stochastic fragments into expression vectors (by ligation) (page 1-2), and in turn, produces a large population of new proteins by host cell expression, followed by screening for proteins or polynucleotides presenting the desired

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properties such as ligand binding, and isolating the polynucleotide encoding the ligand-binding peptide (page 2).

Thus, every limitation present in the claims in the current invention is anticipated by Ballivet *et al.*

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Wang whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Louise Wang, Ph.D.
Patent Examiner
19 September 2005


JEFFREY STUCKER
PRIMARY EXAMINER